

Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- **Mandatory** – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- **Conditional** – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- **Optional** – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- **Non-harmonized** – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

PET Imaging Agent CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- AG – Procedure Agents (v3.3)

PET Imaging Agent CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Agent Lot Number Identifier (m) 7104554 AGLOT	A unique identifier assigned to the lot number of the procedure agent. CDASH: No Match; SDTM: AGLOT (7104554)	CHARACTER
Radionuclide Imaging Agent Source Type (m) 7104558 AGAGTSRC	The origin of the radionuclide imaging agent. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Radionuclide Imaging Agent Administered Indicator (m) 7104573 AGRNADM	An indication whether or not a radionuclide imaging agent was administered. CDASH: No Match; SDTM: ACOCCUR (6841824) where AGTRT = Agent Name and AGSCAT = "Imaging Agent Administered"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Radionuclide Imaging Agent Administration Start Date (m) 7104574 AGSTDTC	The date the radionuclide imaging agent was administered represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: AGSTDAT(6790381)	DATE
Radionuclide Imaging Agent Route of Administration Type (m) 7104575 AGRNROUT	The route of administration of the radionuclide imaging agent. CDASH: No Match; SDTM: AGROUTE (No CDE)	CHARACTER. Use choice list.
Procedure Agent Injection Site Code (m) 7072161 AGLOC	The code assigned to the anatomic site where a contrast agent was administered intravenously. CDASH: No Match; SDTM: AGLOC (7072161)	CHARACTER. Use choice list.
Procedure Agent Injection Site Text (m) 7104577 AGLOCX	The description of the anatomic site of the radionuclide imaging agent injection. CDASH: No Match; SDTM: AGLOC (No CDE)	CHARACTER
Radionuclide Imaging Agent Prior Injection Method of Administration Dose Assay Radioactive Activity Value (m) 7104578 AGSYRACT	The radioactive activity of the radionuclide imaging agent prior to injection represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER
Dose Units (m) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Radionuclide Imaging Agent Prior Injection Dose Assay Radioactive Activity Time (m) 7104579 AGSYRTM	The time that the radioactive activity dose assay was performed before injection of the radionuclide imaging agent. CDASH: No Match; SDTM: No Match	CHARACTER
Radionuclide Imaging Agent Injection Start Time (m) 7104580 AGINJTM	The time the radionuclide imaging agent was injected. CDASH: No Match; SDTM: AGSTDTC (6790381)	CHARACTER
Radionuclide Imaging Agent Post Injection Method of Administration Residual Dose Assay Radioactive Activity Value (m) 7104581 AGRSDACT	The radioactive activity of the residual radionuclide imaging agent after injection represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER
Dose Units (m) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.
Radionuclide Imaging Agent Post Injection Method of Administration Residual Dose Assay Radioactive Activity Time (m) 7104582 AGRSDTM	The time that the radioactive activity dose assay was performed after injection of the radionuclide imaging agent. CDASH: No Match; SDTM: No Match	CHARACTER
Radionuclide Imaging Agent Injection Method of Administration Timepoint Dose Assay Net Radioactive Activity Value (m) 7104583 AGNETACT	The radioactive activity of the radionuclide imaging agent at the time of injection represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Dose Units (m) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.
Radionuclide Imaging Agent Infiltration Type (m) 7104584 AGISOFLT	The extent of the diffusion or accumulation of radionuclide imaging agent in tissue or cells. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Radionuclide Imaging Agent Administered Name (m) 7104585 AGRNUCNM	The name of the radionuclide imaging agent. CDASH: No Match; SDTM: AGTRT (No CDE)	CHARACTER. Use choice list.
Radionuclide Imaging Agent Prior Injection Method of Administration Negation Hypersensitivity Confirmation Indicator (m) 7104586 AGNALLRG	An indication whether or not there was confirmation that the patient had no known allergies to the radionuclide imaging agent prior to injection. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Agent Supplier Name (c) 2971977 AGT_SUPP_NM	Text identification of the business or organization is supplying an agent. Not for FDA submission	CHARACTER
Radionuclide Imaging Agent Manufacture Method Text (o) 7104587 AGMNF CMD	The description of the method used to manufacture the radionuclide imaging agent. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Radionuclide Imaging Agent Assay Timepoint Dose Assay Net Radioactive Activity Value (o) 7104588 AGISOACT	The net radioactive activity of the radionuclide imaging agent at the time of the dose assay represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER
Dose Units (o) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.
Radionuclide Imaging Agent Pyrogenicity/Endotoxin Assessment Outcome Type (o) 7104589 AGPYRRSL	The description of the success of the pyrogenicity assessment. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Radionuclide Imaging Agent Radiopharmaceutical Compound Purity Assessment Value (o) 7104590 AGRDIORS	The purity of the radionuclide imaging agent test represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER
Radionuclide Imaging Agent Radionuclide Specific Activity Value (o) 7104591 AGRDIQVL	The ratio of radionuclide activity to the total mass of the element present represented as a numerical value. CDASH: No Match; SDTM: No Match	NUMBER
Dose Units (o) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.

Annotated CRF: PET Imaging Agent CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: PET Imaging Agent CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Study Treatment Identification Number (7104554) CDE Short Name: AGLOT</p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: AGLOT (7104554)</div>	<p>CHARACTER – Maximum Length = 40</p>
<p>PET imaging agent source (7104558) CDE Short Name: AGAGTSRC</p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: No Match, Can be a supplemental qualifier in SDTM</div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obtained from outside supplier – Obtained from outside supplier <input type="checkbox"/> Prepared in-house – Prepared in-house <input type="checkbox"/> Purchased – Purchased <input type="checkbox"/> Synthesized – Synthesized
<p>Was imaging agent administered? (7104574) CDE Short Name: AGRNADM</p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: ACOCCUR (6841824) where AGTRT = Agent Name and AGSCAT = "Imaging Agent Administered"</div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes
<p>Date Agent Administered (7104574) CDE Short Name: AGSTDTC</p> <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: AGSTDAT(6790381)</div>	<p>DATE – Maximum Length = 11</p>

CRF Question	Value Domain
<p>Route of Administration (7104575) CDE Short Name: AGRNROUT</p> <p>CDASH: No Match</p> <p>SDTM: AGROUTE (No CDE)</p>	<p>CHARACTER – Maximum Length = 25</p> <p>List of 39 PVs</p>
<p>Location of injection site (7072161) CDE Short Name: AGLOC</p> <p>CDASH: No Match</p> <p>SDTM: AGLOC (7072161)</p>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1 – Right antecubital <input type="checkbox"/> 2 – Right wrist <input type="checkbox"/> 3 – Left antecubital <input type="checkbox"/> 4 – Left wrist <input type="checkbox"/> 5 – Right foot <input type="checkbox"/> 6 – Left foot <input type="checkbox"/> 88 – Other specify <input type="checkbox"/> 99 – Unknown
<p>Location of injection site, Other specify (7104577) CDE Short Name: AGLOCX</p> <p>CDASH: No Match</p> <p>SDTM: AGLOC (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Activity in full syringe before injection (7104578) CDE Short Name: AGSYRACT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Dose Units (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> mCi – Millicurie

CRF Question	Value Domain
<p>Time of assay of full syringe before injection (7104579) CDE Short Name: AGSYRTM</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Time of injection (7104580) CDE Short Name: AGINJTM</p> <p>CDASH: No Match</p> <p>SDTM: AGSTDTC (6790381)</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Residual activity in syringe after injection (7104581) CDE Short Name: AGRSDACT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Dose Units (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mCi – Millicurie</p>
<p>Time of assay of residual activity after injection (7104582) CDE Short Name: AGRSDTM</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Net activity at the time of injection (7104583) CDE Short Name: AGNETACT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Dose Units (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mCi – Millicurie</p>
<p>Any imaging agent infiltration at injection site noted? (7104584) CDE Short Name: AGISOFLT</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 25</p> <p><input type="checkbox"/> Minor (<= 20% of dose) – Minor infiltration is estimated to be less than or equal to 20% of dose</p> <p><input type="checkbox"/> None – No infiltration of radiotracer</p> <p><input type="checkbox"/> Severe (> 20% of dose) – Severe infiltration is estimated to be more than 20% of dose</p>
<p>PET imaging agent name (7104585) CDE Short Name: AGRNUCNM</p> <p>CDASH: No Match</p> <p>SDTM: AGTRT (No CDE)</p>	<p>CHARACTER – Maximum Length = 40</p> <p><input type="checkbox"/> Cu-64 ATSM – Cu-64 ATSM</p> <p><input type="checkbox"/> F-18 FDG – F-18 FDG</p> <p><input type="checkbox"/> F-18 FLT – F-18 FLT</p> <p><input type="checkbox"/> F-18 Fluoride – F-18 Fluoride</p> <p><input type="checkbox"/> F-18 Fluorodihydrotestosterone (FDHT) – F-18 Fluorodihydrotestosterone (FDHT)</p> <p><input type="checkbox"/> F-18 Fluorodopa – F-18 Fluorodopa</p> <p><input type="checkbox"/> F-18 Fluoroestradiol (FES) – F-18 Fluoroestradiol (FES)</p> <p><input type="checkbox"/> F-18 FMISO – F-18 FMISO</p> <p><input type="checkbox"/> FDG – FDG</p> <p><input type="checkbox"/> Ga-68 DOTA-NOC – Ga-68 DOTA-NOC</p> <p><input type="checkbox"/> Ga-68 DOTATOC – Ga-68 DOTATOC</p> <p><input type="checkbox"/> I -124 Iodide – I -124 Iodide</p>
<p>Confirmed patient with no allergy to contrast agent prior to administration (7104586) CDE Short Name: AGNALLRG</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>

Conditional Questions

CRF Question	Value Domain
<p>Supplier (2971977) CDE Short Name: AGT_SUPP_NM</p> <p>CDASH: Not for FDA submission</p> <p>SDTM: Not for FDA submission</p>	<p>CHARACTER – Maximum Length 24</p>

Optional Questions

CRF Question	Value Domain
<p>Method [of synthesis] (7104587) CDE Short Name: AGMNF CMD</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Net activity at time of assay (7104588) CDE Short Name: [AGISOACT</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Dose Units (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mCi – Millicurie</p>
<p>Pyrogen test results (7104589) CDE Short Name: AGPYRRSL</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 8</p> <p><input type="checkbox"/> Failed – Failed</p> <p><input type="checkbox"/> Not Done – Not Done</p> <p><input type="checkbox"/> Passed – Passed</p>
<p>Radiochemical purity test result (7104590) CDE Short Name: AGRDIORS</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Specific Activity (7104591) CDE Short Name: AGRDIOVL</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Dose Units (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mCi/kg – Millicurie per Kilogram</p>